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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/938,667 | 08/27/2001 | Jens Petersen | 60117.000006 | 2505 |
| 7590 Stanislaus Aksman Hunton & Williams Suite 1200 1900 K Street, N.W. Washington, DC 20006 | | | EXAMINER FUBARA, BLESSING M | |
| | | | ART UNIT 1615 | PAPER NUMBER |
| DATE MAILED: 10/14/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,667

Applicant(s)

PETERSEN

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-20,23,24,26 and 28-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-15,17-20,23,24,26 and 28-61 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/8, 9/2 & 9/16/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 04/08/04, 09/02/04 and 09/16/04; request for extension of time, amendment and remarks filed 06/29/04. Claims 1-7, 9-20, 23, 24, 26, 28-49 and new claims 50-61 are pending.

Claim Rejections - 35 USC § 102

1. Claims 1-7, 18, 20, 26, 28, 41-46 and 50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pavlyk (RU 2034465, provided by applicants).

Applicant states that Pavlyk does not disclose all the limitations of the claims and that the examiner acknowledged, "that the amount of monomer units in the hydrogel is not disclosed."

2. Applicant's arguments filed 06/29/04 have been fully considered but they are not persuasive.

Pavlyk clearly discloses hydrogel composition that contains 3.5-9% acrylamide, 0.001-1% methylene-bis-acrylamide and about 82% bi-distilled water. Excess acrylamide is not disclosed. Examiner only stated that Pavlyk did not refer to free monomeric units in the hydrogel composition and Examiner in that statement referenced by applicant was responding to applicant's argument of 08/13/02, "that the claimed hydrogel's characteristics of being substantially free of monomeric units render patentable the claimed invention," by pointing out that Pavlyk does not make any reference to free monomeric units in the hydrogel.

3. Claims 1, 3, 5, 6, 18, 20, 26, 41, 46, 47 and 50 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/04943 (provided by applicants).

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Applicant states that the WO 96/04943 does not disclose all the limitations of the claims and that the examiner acknowledged, "that the amount of monomer units in the hydrogel is not disclosed."

The WO 96/04943 clearly discloses hydrogel composition that comprises cross-linked polymer and the cross-linking agent is methylene bis-acrylamide. Excess acrylamide is not disclosed. Examiner only stated that WO 96/04943 did not refer to free monomeric units in the hydrogel composition and Examiner in that statement referenced by applicant was responding to applicant's argument of 08/13/02, "that the claimed hydrogel's characteristics of being substantially free of monomeric units render patentable the claimed invention," by pointing out that WO 96/04943 does not make any reference to free monomeric units in the hydrogel.

Claim Rejections - 35 USC § 103

4. Claims 1-7, 9-15, 18-20, 23, 24, 26, 28-36, 41-61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028).

Applicant argues:

Vogel does not disclose or suggest applicant's hydrogel.

Vogel's polymer includes a block copolymer of cell adhesion promoters, such as gelatin and acrylamide, which means that Vogel's polymer does not consist essentially of acrylamide and a cross-linking agent and that Vogel does not teach a hydrogel that is suitable for treatment of incontinence.

Even if Vogel's hydrogel composition is identical to the claimed hydrogel, applicant's hydrogel is patentably distinct from that taught by Vogel because "Vogel does not teach, disclose or suggest Applicant's claimed product: a

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hydrogel that is in a form suitable for the treatment of incontinence or vesicoureteral reflux which is substantially homogenous.”

Vogel’s hydrogel is not directly injected with a syringe; rather the microparticles are first placed in a suspension or formulated into solutions before injecting. Thus Vogel does not teach or suggest all the limitations of the claimed invention.

The claimed hydrogel “is injected into one of the ureter, urethra, colon or rectum, all of which are excretory conduits” and not muscles as disclosed by Vogel.

Applicant concludes that one of ordinary skill in the art “would not be motivated to directly inject a hydrogel into an excretory conduit to treat incontinence based on a reference that teaches injection of a suspension of microparticles and serum into a bladder muscle.”

5. Applicant’s arguments filed 06/29/04 have been fully considered but they are not persuasive.

Vogel discloses the hydrogel of the claimed invention since Vogel’s polymer is made from acrylamide and methylene bis-acrylamide.

Vogel does not disclose block copolymer of cell adhesion promoters and applicant is not definite on the assumption that Vogel discloses block copolymer of cell adhesion promoters. A form suitable for treating incontinence is any form and treating incontinence with a composition is a future intended use that is not critical to a composition or device or product claim. However, Vogel discloses treating incontinence.

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Vogel discloses treating incontinence by injecting the hydrogel composition via the urethra (column 10, line 42) into the walls of the bladder sphincter and the urethra is an excretory conduit as stated by applicant.

Vogel discloses injecting the composition and a syringe is one of the obvious means of injections. Although applicant states that Vogel's hydrogel composition is injected as an emulsion or a solution, it is respectfully noted that the composition is injected and for it to be injected by a syringe, the formulation has to be in a form such as a solution or emulsion. Also the emulsion or solution contains the hydrogel. Applicant is not clear if applicant intended to indicate that the hydrogel of the instant claims is injected as a solid or is it injected as a solution?

In conclusion, it is noted that one of ordinary skill in the art would be motivated to inject the hydrogel via urethra into the bladder sphincter. Since the goal is to treat incontinence, one of ordinary skill in the art would have the skills necessary to administer the hydrogel composition to effect the urethra/bladder.

Other Matters:

Applicant inquired about the arguments submitted with the RCE, and specifically regarding the claim language of "consisting essentially of."

The RCE request of 12/08/03 requested consideration of the amendments filed 10/06/03. The amendment filed 10/06/03 was filed after final rejection and was not entered at that time. But the amendment was considered and entered in response to the request. The RCE did not specifically ask for the remarks filed with the amendments to be considered or were any remarks filed with the RCE. However, the issue is that the amended claim recites "the polymer consisting of a polymer prepared by polymerizing

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acrylamide in the presence of a cross-linking agent..." Now, the biostable hydrogel comprises and thus the hydrogel composition can contain ingredients other than the components that make up the hydrogel. Applicant presented no comparable data to show that the hydrogel composition of the applicant has unusual results over the hydrogel composition of the prior art.

6. Claim 16 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

Applicant acknowledges the rejection under obviousness type double patenting and requests that the rejection be held in abeyance until allowable subject matter is identified/indicated. However the rejection is maintained and is reiterated below.

7. Claims 1-7, 9-15, 18-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 09/938,668 (published as US 2003/0065389). Although the conflicting claims are not identical, they are not patentably distinct from each other because the having monomeric units of less than 50 ppm does not distinguish the examine application over the co-pending application. The composition of the polymer is the same in both applications and administering the composition would inherently treat arthritis and incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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8. Claims 1-7, 9-15, 18-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 09/938,669 (published as US 2002/0150550). Although the conflicting claims are not identical, they are not patentably distinct from each other because the polymeric compositions of both applications are the same and having monomeric units of less than 50 ppm does not distinguish the examined application over the co-pending application. The composition of the polymer is the same in both applications and the compositions can be used as tissue filler endoprosthesis as well as for treating incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-7, 9-15, 17-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 09/938,670 (published as US 2002/0064512). Although the conflicting claims are not identical, they are not patentably distinct from each other because the polymeric compositions of both applications are the same and having monomeric units of less than 50 ppm does not distinguish the examined application over the co-pending application. The composition of the polymer is the same in both applications and the compositions can be used for treating cosmetic or functional defect as well as for treating incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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